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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,406	04/11/2001	Ronald Erwin Boch	273012011300	3418

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/833,406

Applicant(s)
Boch

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

Art Unit: :1615

DETAILED ACTION

The preliminary amendment dated 4-12-02 and the change of address dated 5-9-02 are acknowledged.

Claims included in the prosecution are 21-40.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The negative limitations, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claims 21 and 40, ‘do not comprise egg phospholipid’ in claim 30, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claim 32, ‘but does not comprise vertiporfin’ in claim 33 do not have support in the specification as originally filed and therefore, deemed to be new matter .**

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: :1615

4. Claims 23, 28, 31, 34, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The examiner suggests the incorporation of full chemical names for the photosensitizers in claims 23, 31 and 34 and for AP in claim 28.

The term 'high' in claims 38 and 39 is a relative term and hence deemed to be indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21-25, 29, 32-33 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).

Madden discloses liposome formulations containing BPD-MA, DMPC (saturated lipid) and PC (unsaturated lipid). The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims).

Art Unit: :1615

7. Claims 21-24, 27-29, 32-33, 35-36, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (5,707,608) or Desai (6,074,666) both are of record.

Liu discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 6-12, Examples and claims).

Similarly, Desai discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 3-7, Examples and claims).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 25-30, 32, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden cited above.

As pointed out above, Madden discloses liposome formulations containing BPD-MA, DMPC and PC. The method of preparation involves the mixing the agents and the lipids,

Art Unit: :1615

evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims).

Although through specific examples, Madden shows the liposome formulations using DMPC and egg PC, on col. 7, line 67 through col. 8, lines 25 he teaches the various phospholipids which could be used in the formation of liposomes including DMPG and the rationale for their use (transition temperature). The ratios of the photosensitizer and the phospholipid appear to fall within the claimed ratios. Even assuming they are different, it would have been obvious to one of ordinary skill in the art to use any phospholipid combination taught by Madden and vary the ratios of the porphyrin to the lipid and hydrating at a temperature other than 30 degrees taught by Madden, with the expectation of obtaining the best possible results. The criticality of the specific tubular structure used for the removal of the organic solvent in the method claim is not readily apparent to the examiner since the purpose in both Madden and instant invention is the removal of the solvent irrespective of the structure used. In the absence of showing the criticality, it is deemed that the inclusion of an antioxidant to prevent the oxidation of the lipids and other oxidizable substances would have been obvious to one of ordinary skill in the art since such an inclusion is a routine practice in the art of liposomes.

10. Claims 25-26, 30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu or Desai cited above.

Art Unit: :1615

Although through specific examples, Liu, and Desai show the liposome formulations using a combination of DMPC and egg PG, on col. 7, lines 60-62 (Liu), and col. 6, lines 3-5 (Desai) both teach that other forms of PG, that is, DMPG or DLPG are suitable to use. Therefore, it would have been obvious to one of ordinary skill in the art to select DMPG with the expectation of obtaining the best possible results.

11. Claims 22, 23, 31, 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden or Liu or Desai cited above, in view of applicant's statements of prior art.

The teachings of Madden, Liu and Desai have been discussed above. What is lacking in these references is the teaching of the specific apparatus for the removal of the solvent. Such a use with the expectation of at least similar removal of the solvent however, would have been obvious to one of ordinary skill in the art since applicant on page 40 of the specification indicates that such vacuum drying systems are readily available. What is also lacking in these references is the teachings of the composition in the form of micelles. Applicant on page 28 of the specification indicate that hydration to multilamellar vesicles followed by high energy processing step would result in the formation of micelles. Since the references teach the high energy processing steps, it would have been obvious to one of ordinary skill in the art that the compositions in the prior art would also contain micelles besides liposomes. It would appear that the references do not teach claimed porphyrin derivatives. Applicants in the specification indicate that the claimed derivatives are known

Art Unit: :1615

in the art. The use of art known porphyrins in the liposomes of Madden or Liu or Desai, with the expectation of obtaining at least similar results, would have been obvious to one of ordinary skill in the art since these are photosensitizers with the same basic porphyrin structure

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

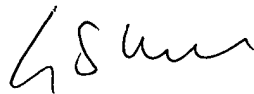
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/833,406

Page 8

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 15, 2002